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Office Action Summary	Application No. 09/905,129	Applicant(s) Einat	
	Examiner Frank Lu	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action* .

DETAILED ACTION

Location of Application

1. The Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1634.

Election/Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 11, 12, and 27, drawn to an isolated nucleic acid molecule (claims 1, 2, 11, 12, and 27) and a composition comprising the isolated nucleic acid molecule (claim 3), classified in class 536, subclass 23.1; a vector comprising the isolated nucleic acid molecule (claim 4) and a composition comprising the vector (claim 5), classified in class 435, subclass 320.1.

II. Claims 6, 7, 10, 21, and 22, drawn to a method for preventing, treating or controlling osteoporosis, or for fraction healing, bone elongation or osteopenia, periodontosis, or low bone density or other conditions involving mechanical stress or a lack thereof in a subject (claim 6), method for preventing, treating or controlling osteoporosis, or for fraction healing, bone elongation or osteopenia, periodontosis, bone fraction or low bone density or other factors causing or contributing to osteoporosis or symptoms thereof or other conditions involving mechanical stress or a lack thereof in a subject (claims 7 and 10), a method for

treating or preventing osteoporosis, or for fraction healing, bone elongation or periodontosis in a subject (claim 21), a method for treating or preventing osteoarthritis, osteoporosis, or osteosclerosis, (claim 22), classified in class 435, subclasses 6 and 7.2.

III. Claims 8 and 9, drawn to a method for preparing a polypeptide comprising expressing the isolated nucleic acid molecule, classified in class 435, subclass 69.1.

IV. Claims 13-18 and 28-30, drawn to an isolated polypeptide (claims 13-17 and 28-30) and a composition comprising one or more isolated polypeptide (claim 18), classified in class 530, subclass 350.

V. Claims 19 and 20, drawn to an antibody (claim 19) and a composition comprising the antibody (claim 20), classified in class 424, subclass 130.1.

VI. Claims 23 and 25, drawn to a receptor for the polypeptide or functional portion thereof, classified in class 530, subclass 350.

VII. Claim 24, drawn to a method of obtaining the receptor, classified in class 435 subclass 6.

VIII. Claim 26, drawn to a method of using the receptor to identifying proteins or polypeptides that bind to, classified in class 435, subclass 7.2.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method in Group III.

Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as the method in Group I.

Groups I and IV are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as polypeptide is not required for Group I.

Groups I and V are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as antibody is not required for Group I.

Group I and Groups VI and VIII are distinct and independent inventions in that they are directed to a product (Group I) and two unrelated methods (Groups VI and VIII) that have different modes of operation, different functions, or different effects. As a result, different and

distinct searches will have to be performed. For example, the search required for Groups VI and VIII such as receptor is not required for Group I.

Groups I and VII are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group VII such as receptor is not required for Group I.

Groups II and III are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as administering an isolated nucleic acid molecule is not required for Group III.

Groups II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as making an antibody.

Groups II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as western blotting.

Group II and Groups VI, VII, and VIII are distinct and independent inventions in that they are directed to a method and a unrelated product and two unrelated methods that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Groups VI, VII, and VIII such as receptor is not required for Group II.

Groups III and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, that the product as claimed can be made by another and materially different process such as the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as direct purification from the cells or *in vitro* synthesis.

Groups III and V are distinct and independent inventions in that they are directed to a method and a unrelated product that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as antibody is not required for Group III.

Groups III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be

used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, that the product as claimed can be made by another and materially different process such as the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as direct purification from the cells.

Group III and Groups VII and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Groups VII and VIII such as receptor is not required for Group III.

Groups IV and V are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as antibody is not required for Group IV.

Groups IV and VI are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group VI such as receptor is not required for Group IV.

Group IV and Groups VII and VIII are distinct and independent inventions in that they are directed to a product and two unrelated methods that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be

performed. For example, the search required for Groups VII and VIII such as receptor is not required for Group IV.

Groups V and VI are distinct and independent inventions in that they are directed to different products that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Group VI such as receptor is not required for Group V.

Group V and Groups VII and VIII are distinct and independent inventions in that they are directed to a product and two unrelated methods that have different modes of operation, different functions, or different effects. As a result, different and distinct searches will have to be performed. For example, the search required for Groups VII and VIII such as receptor is not required for Group V.

Groups VI and VII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by another and materially different process such as a recombination DNA method.

Groups VI and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP §

806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product such as making an antibody of the receptor.

Group VII and Group VIII are distinct and independent inventions in that they are directed to different methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VIII such as binding constant is not required for Group VII.

4. Sequence Election Requirement Applicable to All Groups

Each Group detailed above reads on patentably distinct SEQ ID Numbers. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to each Group. Although the nucleic acid and polypeptides are related as the claimed nucleic acid is asserted to encode the claimed polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the nucleic acid may be used for processes other than the production of the protein as evidenced by the methods of at least Group II. Therefore, applicant must further elect a single SEQ ID NO. (See MPEP 803.04). Applicant is advised that examination will be restricted to only elected SEQ ID NO. and should not to be construed as a species election.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Group II contains claims directed to the following patentably distinct species of the claimed invention:

(1) administering an isolated nucleic acid molecule (claims 6 and 7)

(2) administering an isolated polypeptide (claim 21)

(3) administering an antibody (claim 22)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claim is claim 10.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Group IV contains claims directed to the following patentably distinct species of the claimed invention:

(1) a polypeptide having a molecule weight of 10 kD to 100 kD (claim 16)

(2) a polypeptide having a molecule weight of about 25 kD (claim 17)

(3) a polypeptide having a molecule weight of about 70-80 kD (claim 17)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims are claims 13-15, 18, and 28-30.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Group IV contains claims directed to the following patentably distinct species of the claimed invention:

(1) the first 663 amino acids (claim 29)

(2) the first 241 amino acids (claim 30)

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, generic claims 13-18 and 28.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

An inquiry of a general nature or relating to the status of this application should be directed to the patent Analyst of the Art Unit, Ms. Chantae Dessau, whose telephone number is (703) 605-1237.

Frank Lu
August 5, 2002